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Office Action Summary	Application No.	Applicant(s)	
	09/899,917	OLSEN ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-116* is/are pending in the application.

4a) Of the above claim(s) *29,37,48,54,60,75,82,91,100,108 and 115* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28,30-36,38-47,49-53,55-59,61-74,76-81,83-90,92-99,101-107,109-114 and 116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1 ☐ Certified copies of the priority documents have been received.

2 ☐ Certified copies of the priority documents have been received in Application No. _____ .

3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Applicants' election with traverse of Group I (claims 17-28, 30-36, 38-47, 49-53, 55-59, 61-74, 76-81, 83-90, 92-99, 101-107, 109-114 and 116) in paper #10 (filed on October 21, 2002) is acknowledged. The traversal is on the ground that search of Group I (protein) and Group II (process for making the protein) would largely overlap, furthermore, it is highly unlikely that any prior art exists concerning "traditional synthetic protein synthesis" of the proteins recited by the method claims of group I since the proteins recited therein were unknown prior to their invention by applicants, thus Applicants believe that once a search has been conducted of the proteins of group I, no further search will be required in order to consider the methods of group II. The traversal has been fully considered and not found persuasive because Group I and Group II are directed to product and process of making (see MPEP 806.05(f). Regarding the search overlapping of group I and II it should be noted that a search for a protein product requires a search covering class 530/350, 300+, whereas a search for the recombinant production of the protein requires a search that covers 435/69.1, 252.3, 320.1, 325 and 536/23.5. Therefore, the search for Group I and II doesn't largely overlap as shown by the different classification across the groups. Further, how the existence of a prior art concerning "traditional synthetic protein synthesis" of the proteins recited by the method claims of group I is assumed before doing a search?

Furthermore, the traversal is also on the ground that the method of Group II should also be examined in accordance with *In re Ochiai, In re Brouwer and 35 U.S.C. 103(b)*. Once the product claims are found allowable, the Examiner will consider the allowance of enabled method claims using the allowed product in accordance with *In re Ochiai, In re Brouwer and 35 U.S.C. 103(b)*. However, for initial examination purposes, the subject matter of elected Group I will be examined at this time, there being no currently allowable product claim.

The restriction requirement is still deemed proper and is therefore made **FINAL.**

Claims 29, 37, 48, 54, 60, 75, 82, 91, 100, 108 and 115 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 17-28, 30-36, 38-47, 49-53, 55-59, 61-74, 76-81, 83-90, 92-99, 101-107, 109-114 and 116 are currently pending and are under examination.

Priority

Applicants' claim for domestic priority under 35 U.S.C. 120 is acknowledged. The continuation data on page 1 of the specification should be updated.

Information Disclosure Statement

The information disclosure statement filed on October 4, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because an English translation of the reference WO99/18205 (document AL1) listed in PTO Form 1449 has not been provided. Therefore the information referred to therein has not been considered as to the merits and lined through, however, an English language equivalent document (Honjo et al., US 2002/0086364 A1, July 4, 2002) has been considered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 17-28, 30-36, 38-47, 49-53, 55-59, 61-74, 76-81, 83-90, 92-99, 101-107, 109-114 and 116 are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed proteins are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed proteins or the polynucleotides encoding these proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed proteins or the polynucleotides

encoding them such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

The specification, on page 20 describes an isolated protein, the Human Oncogene Induced Secreted Protein I (HOIPS I) encoded by the deposited cDNA clone (ATCC NO: 97825) to which the instant invention relates. Applicants assert (page 8, lines 13-16) that the HOIPS I protein is said to share homology with chicken MD-1 protein (45%). However, this structural homology is not correlated with any function that the chicken-MD1 protein may have. At page 16, line 28, the specification indicates that deposited cDNA encodes a polypeptide having HOIPS I activity. By a polypeptide having HOIPS I activity it is intended polypeptides exhibiting activity similar, but not necessarily identical, to an activity of the HOIPS I protein. No activity of the HOIPS I protein is provided in the specification. Therefore, the utility of a HOIPS I polypeptide encoded by a cDNA is not a substantial utility because there is no real world context in which to use a protein having no known activity. This situation requires carrying out future research to identify the activity of the protein or reasonably confirm a "real world" context of use and therefore does not define substantial utility.

Other activities that the protein may exhibit are listed throughout page 26-35 of the specification. The specification teaches that it is believed that certain tissues in mammals with cancer, in particular acute myelogenous leukemia, express significantly altered levels of HOIPS I and mRNA encoding HOIPS I. No evidence for this belief is provided. Further, the diagnosis will occur by comparing mRNA encoding HOIPS I to a corresponding standard mammal not having cancer, and that enhanced level is indicative of leukemia. There is no teachings provided in regarding the levels of HOIPSI mRNA in a standard mammal, or how this control and test sample will be standardized. Moreover, in Northern Blot, for example, the intensity of the band of mRNA encoding HOIPS I is an indication of the abundance of the message of the mRNA molecule, rather than an indication of leukemia. The amount of mRNA cannot be standardized, that is, the cells would be mixed with some overexpressing HOIPS I mRNA and some not, noting that tumors vary in size and composition. Therefore, these utilities are not substantial utilities because there is no real world context to use these methods of diagnosing myelomas

without further research to confirm this utility. The utilization of the HOIPS I gene and its product in gene therapy and other therapeutics have been described in pages 28-35. However, generalized statements regarding the activity of the gene product are set forth at pages 28-35. In summary, the polypeptides claimed do not have a credible, specific or well-established or even demonstrable utility and therefore lacks utility under 35 U.S.C. 101.

Claims 17, 18, 20-26, 30, 39, 40, 42, 43, 45, 49, 62-72, 76-79, 83, 84-88, 92-97 and 101 are drawn to a protein comprising a fragment of SEQ ID 2. The specification does not describe the functional properties of the entire protein or its fragments, and the structural information is limited, it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed fragments for which no known activity is explicitly disclosed nor demonstrated.

Claims 31-34, 38, 50, 51, 55-57 and 61 are drawn to a mutant generated from the amino acid sequence set forth in SEQ ID 2. The specification does not describe the functional properties of these mutants, and the structural information is limited, it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed mutants for which no known activity is explicitly disclosed nor demonstrated.

Claims 39-44, 50, 56, 93, 102, 104, 110 and 111 are drawn to proteins or a fragment encoded by the cDNA of clone in ATCC deposit No. 97825. It is not clear from the description of the clone (specification pages 8-9) about the protein structure, aside from its amino acid sequence, and/or its function. As discussed above, based on the specification (pages 8-9) it is unclear what activity the claimed proteins possess, what activity the polynucleotides encoding the proteins or protein fragments possess.

Claims 28, 36, 47, 53, 59, 74, 81, 90, 99, 107 and 114 are directed to a composition comprising the protein of claims 17, 31, 39, 50, 56, 62, 77, 84, 93, 102, 110 and a pharmaceutically acceptable carrier. The speculative composition and their administration and dosage are listed in the specification (pages 31-35), however when the proteins claimed lack a credible, specific or well established utility, the composition of those proteins would also lack utility under 35 U.S.C. 101.

Claims 27, 35, 46, 52, 58, 73, 80, 89, 98, 106 and 113 are drawn to a protein of claims 17, 31, 39, 50, 56, 62, 77, 84, 93, 102 and 110 respectively, which comprises a heterologous polypeptide sequence. It is not clear from the description on page 19 about the heterologous protein structure, and /or its function.

In the instant case, the failure of the specification to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the protein set forth in SEQ ID NO: 2 or for the polynucleotides of SEQ ID NO: 1 encoding the protein other than the fact that the protein may have a similar activity of HOIPS I protein (p. 20). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 2 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-28, 30-36, 38-47, 49-53, 55-59, 61-74, 76-81, 83-90, 92-99, 101-107, 109-114 and 116 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 39-44, 50, 56, 93, 102, 104, 110 and 111 and dependent claims thereto are rejected because claims recite necessity of a deposited clone, ATCC 97825, and do not meet fully with the deposit requirements set. The specification at page 5 indicates that the deposit of clone has been made with ATCC and were given the Accession number ATCC 97825. However, Applicants fail to provide a copy of the deposit receipt. Submission of a copy of the receipt would overcome this rejection.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 20-25, 32, 33, 39-44, 50, 56, 62, 93, 102, 104, 110 and 111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39-44, 50, 56, 93, 102, 104, 110 and 111 contains the trademark/trade name ATCC. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a cDNA clone and, accordingly, the identification/description is indefinite. Please spell out the full words for the acronym instead.

Claims 20-25, 32, 33, 62(a) are indefinite because of using a minus (-) sign preceding an amino acid residue. Is that particular amino acid fragment's position is located in the non-coding sequence region? Deletion of minus sign (-) would overcome this rejection.

Claim 102 and 104 are indefinite as to "nucleic acid encoded by the cDNA." How a cDNA encodes a nucleic acid instead of encoding a protein sequence?

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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